



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

BIOMERIEUX, INC.  
PATENT DEPARTMENT  
100 RODOLPHE STREET  
DURHAM NC 27712

**MAILED**

SEP 28, 2009

OFFICE OF PETITIONS

In re Patent No. 7,429,355  
Issued: September 30, 2008  
Application No. 10/695,517  
Filed: October 28, 2003  
Attorney Docket No. 01051

:  
: DECISION ON APPLICATION  
: FOR PATENT TERM ADJUSTMENT  
:  
:  
:

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. 1.705 (b)-(d)" filed November 13, 2008, requesting that the patent term adjustment determination for the above-identified patent be changed from eight hundred ninety-two (892) days to one thousand three hundred sixty-one (1361) days.

The request for reconsideration of patent term adjustment is **DISMISSED**.

On September 30, 2008, the above-identified application matured into US Patent No. 7,429,355 with a patent term adjustment of 892 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that in view of the decision in Wyeth, they are entitled to a patent term adjustment of 1361 days (702 (Three Years Delay) plus 902 (Examination delay) reduced by 233 (overlap) minus 10 (applicant delay).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In

other words, it is the period of Office delay reduced by the period of applicant delay. Patentees do not dispute the period of reduction of 10 days for applicant delay. Patentees argue that the total period of Office delay is the sum of the period of Three Years Delay (702 days) and the period of Examination Delay (902 days) to the extent that these periods of delay are not overlapping. Patentees contend that the periods of examination delay and the Three Years Delay overlap by 233 days. As such, patentees assert entitlement to a patent term adjustment of 1361 days (702 + 902 reduced by 233 overlap - 10 for applicant delay).

At the outset, the Office notes that as of the issuance of the patent, the application was pending three years and 703 (not 702) days after its filing date (October 29, 2006 to September 30, 2008). The Office agrees that the action detailed above was not taken within the specified time frame, and thus, a period of adjustment under 37 CFR 1.702(a)(1) of 902 days was entered. At issue is whether patentees should accrue 703 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 902 days for the Office failing to take a certain action within a specified time frame (or examination delay).

The Office contends that 703 days overlap. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods

excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) to the extent

that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718<sup>1</sup>

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, October 28, 2003, to the date the patent issued on September 30, 2008. (There were no periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). Prior to the issuance of the patent, 902 days of patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application. All of the 703 days for Office delay in issuing the patent overlap with the 902 days of Examination delay. During that time, the issuance of the patent was delayed by 902 days, not 902 + 703 days. The Office experienced 902 days of examination delay. Otherwise, the Office took all actions set forth in 37 CFR 1.702(a) within the prescribed time frames. Nonetheless, given the 902 days of Office delay and the time allowed within the time frames for processing and examination, as of the date the patent issued, the application was pending three years and 703 days. The Office did not delay 902 days and then an additional 703 days. Entry of both periods is not warranted. Thus, 902 days is determined to be the actual number of days that the issuance of the patent was delayed, considering the 703 days over three years to the issuance of the patent.

Accordingly, at issuance, the Office properly entered no additional days of patent term adjustment for the Office taking in excess of three years to issue the patent.

In view thereof, no adjustment to the patent term will be made.

---

<sup>1</sup> The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

Telephone inquiries specific to this decision should be directed to Senior Petitions Attorney Patricia Faison-Ball at (571) 272-3212.

*Christina Patrice Donnell for*

Kery A. Fries  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of Deputy Commissioner  
for Examination Policy